REMARKS

1. In response to the Office Action mailed April 6, 2009, Applicants respectfully request reconsideration. Claims 38-46 were last presented for examination, and claims 47 and 48 were withdrawn. In the outstanding Office Action, claims 38-46 were rejected. By the foregoing Amendments, claims 38, 40, 42, and 44 have been amended. Claims 51-53 have been added, and claim 39 has been cancelled. Thus, upon entry of this paper, claims 38, 40-46, 51-53, and withdrawn claims 47-48 will be pending in this application. Of these thirteen (13) claims, 1 claim (claim 38) is independent.

2. Based upon the above Amendments and following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

Priority Claim

3. Applicants request that the Examiner acknowledge Applicants' claim of foreign priority under 35 U.S.C. §119, and request the Examiner acknowledge that certified copies of the priority documents have been received.

Claim Rejections under §112, Second Paragraph

4. The Examiner has rejected claims 38-46 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite.

5. The Examiner rejected claim 38 because of the presence of the term "and/or" in claim 38. Applicants have removed that term from claim 38. In addition, the Examiner rejected claim 40 because the term "the cochleostomy site" lacked antecedent basis. Claim 40 now recites "a cochleostomy site."

6. Accordingly, Applicants respectfully request that the rejections of claims 38-46 under 35 U.S.C. 112, second paragraph, be withdrawn.

Claim Rejections under §102 in view of Kuzma

7. The Examiner has rejected claims 38-40 and 42-45 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,309,410 to Kuzma et al. (hereinafter, "Kuzma"). Applicants respectfully disagree.

8. Kuzma is directed to "implantable stimulation devices, e.g., cochlear prosthesis used to electrically stimulate the auditory nerve, and more particularly to an electrode array having a drug delivery channel formed therein." (*See*, Kuzma, col. 1, lines 16-19.) Kuzma discloses that "an electrode positioner is used with the electrode array to press or hold the electrode contacts of the array against the modiolar wall of the cochlea." (*See*, Kuzma, col. 3, lines 62-64.) In addition, Kuzma teaches that "[a] drug delivery channel is formed within the body of the electrode array and/or the within the body of the positioner, allowing drugs to be administered through such channel." (*See*, Kuzma, col. 3, lines 64-67.) For example, Kuzma illustrates a positioner 20 in FIGS. 2A and 2B, and further illustrates a channel 25' in positioner 20 that may be a drug delivery channel. (*See*, Kuzma, col. 6, lines 18-21; and FIGS. 2A and 2B.)

9. Applicants' claim 38 recites, in part, "[a]n implantable tissue-stimulating device comprising: a lead extending along a longitudinal axis and having a circumference in a plane perpendicular to the longitudinal axis." Claim 38 further recites, in part, "a bioactive substance delivery means . . . wherein the substance delivery means is configured to surround at least a majority of the circumference of the lead." (*See*, Applicants' claim 38, above.) Applicants submit that Kuzma, as relied upon by the Examiner, fails to disclose "wherein the substance delivery means is configured to surround at least a majority of the circumference of the lead," as recited in Applicants' claim 38, for at least the following reason(s).

10. The Examiner alleges that the electrode array 10 of Kuzma corresponds to the lead recited in Applicants' claim 38, and that the positioner 20 of Kuzma corresponds to the substance delivery means recited in claim 38. (*See*, Office Action, page 3.) However, Applicants submit that Kuzma fails to disclose that positioner 20 of Kuzma "is configured to surround at least a majority of the circumference of the lead," as recited in Applicants' claim 38.

11. FIGS. 1B and 2B of Kuzma each show cross-sections of electrode array 10 and positioner 20. (*See*, Kuzma, col. 5, lines 6-8 and 13-17; and FIGS. 1B and 2B.) As illustrated in each of

FIGS. 1B and 2B of Kuzma, positioner 20 is not configured to surround at least a majority of the circumference of electrode array 10 of Kuzma. Rather, Applicants submit that FIGS. 1B and 2B each show that positioner 20 surrounds less than a majority of the circumference of electrode array 10.

12. Additionally, the Examiner appears to assert that, in FIG. 2, positioner 20 of Kuzma "is annular/around the lead in the plane of the page." (*See*, Office Action, page 4.) However, claim 38 recites "a lead extending along a longitudinal axis and having a circumference in a plane perpendicular to the longitudinal axis." Thus, in Applicants' claim 38, the circumference of the lead is "in a plane perpendicular to the longitudinal axis" along which the lead extends. (*See*, Applicants' claim 38, above.) However, Applicants submit that FIG. 2A does not show positioner 20 configured to surround at least a majority of the circumference of electrode array 10 where the circumference is in a plane perpendicular to a longitudinal axis along which electrode array 10 extends.

13. Applicants, therefore, respectfully submit that Kuzma fails to anticipate or render obvious "a lead extending along a longitudinal axis and having a circumference in a plane perpendicular to the longitudinal axis ... and ... a bioactive substance delivery means . . . wherein the substance delivery means is configured to surround at least a majority of the circumference of the lead," as recited in Applicants claim 1. For at least this reason, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. §102 over Kuzma be reconsidered and withdrawn.

Claim Rejections under §102 in view of Kramm

14. The Examiner has rejected claims 38-40 and 42-45 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,936,040 to Kramm et al. (hereinafter, "Kramm"). Applicants respectfully disagree.

15. Applicants' claim 38 recites, in part, "[a]n implantable tissue-stimulating device comprising . . . a resiliently flexible elongate member extending from the lead and having a proximal end and a distal end and at least one electrode mounted thereon between said proximal and distal ends for delivering electrical stimulation specified at least in part by a speech processor." Applicants submit that Kramm fails to disclose "at least one electrode . . . for

delivering electrical stimulation specified at least in part by a speech processor," as recited in Applicants' claim 38, for at least the following reason(s).

16. Kramm is directed to "a method and apparatus for positioning and fixating an electrode lead to stimulate and/or sense activity in the heart." (*See*, Kramm, col. 1, lines 9-10.) Kramm teaches "an endovenous epicardial lead 14." (*See*, Kramm, col. 5, lines 7-8; *see also* FIG. 2.) Kramm also teaches a "guide catheter 40." (*See*, Kramm, col. 5, lines 32; *see also* FIG. 3.)

17. Kramm discloses that "guide catheter 40 includes a flexible tubular body 42 having a distal end 44 and a proximal end 46." (*See*, Kramm, col. 5, lines 32-34.) In addition, Kramm teaches that "[an] axial lumen 52 of the tubular body 42 provides a passageway for a lead (e.g., an electrical lead) to be directed out of the distal end 44 of the catheter 40." (*See*, Kramm, col. 5, lines 37-39.) However, Kramm discloses that "[t]his invention relates generally to a method and apparatus for electrically stimulating a heart." (See, Kramm, col. 1, lines 7-8.) As such, Kramm fails to disclose a speech processor. Thus, while Kramm discloses an electrical lead, Applicants submit that Kramm fails to anticipate or render obvious "at least one electrode . . . for delivering electrical stimulation specified at least in part by a speech processor," as recited in Applicants' claim 38.

18. For at least the reason(s) set forth above, Applicants respectfully request that the rejection of claim 38 under 35 U.S.C. §102 over Kramm be reconsidered and withdrawn.

Dependent Claims

19. The dependent claims incorporate all the subject matter of the independent claim and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

20. In addition, Applicants' claim 40, as amended, recites "an inlet disposed in a proximal end of the body; wherein the outlet is disposed in a distal end of the body; and wherein the substance delivery means and the lead are configured such that, after implantation of the device, the outlet of the substance delivery means is located external and adjacent to a cochleostomy site." (*See*, Applicants' claim 40, above.) Accordingly, Applicants request that the rejections of claim 40 be reconsidered and withdrawn for this additional reason.

New Claims

21. Applicants submit that claims 51-53 are dependent claims and are therefore allowable over the art of record for at least the reason that the claims incorporate the subject matter of the independent claim.

Conclusion

22. In view of the foregoing, this application should be in condition for allowance. A notice to this effect is respectfully requested.

23. Applicants reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Any cancellations and amendments of the above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and Applicants reserve the right to pursue such claims in a continuation or divisional application.

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Respectfully submitted,

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